REMARKS

Claims 11, 12, 17, 20-22, 24, and 27-32 are pending in the current application. Claims 11, 28, 30, and 31 have been amended, leaving Claims 11, 12, 17, 20-22, 24, and 27-32 for consideration upon entry of the present amendment.

Support for the amendment to Claims 11, 28, and 30 can be found at least on Page 2, paragraph 4; page 3, paragraph 1; and the last paragraph on page 3.

Support for the amendment to claim 31 can be found in the claim itself.

Support for the amendments to the 2nd full paragraph on page 2 of the Substitute Specification can be found in the Specification as originally filed.

Support for the amendment to the 1st full paragraph on page 3 of the specification can be found in the paragraph itself as well as throughout page 2 of the specification. Particularly, in the 1st full paragraph on page 3, germs are listed to include "*Candida albicans*, *Shighellas*, *Clostridium*, *Bacillus cereus*, *Staphylococcus aureus*, and *Campylobacter jejuni*". Based on this description and the understanding of one of skill in the art of the term "germs", it is clear that the compositions are suitable for the treatment of sinusitis and rhinitis caused by bacteria and fungi.

No new matter has been introduced by these amendments. Reconsideration is requested in view of the amendments and the following remarks.

Information Disclosure Statement

The Examiner has lined out the International Search Report cited on the Information Disclosure Statement filed July 3, 2003. Applicants submit that the International Search Report was properly cited on the Information Disclosure Statement and request that the Examiner provide a copy of the Information Disclosure Statement with that item initialed with the next Office Action.

Objections Under 35 U.S.C. § 132

The Examiner objects to the material presented in the amendment filed on November 5, 2003 stating that the amendment added material which is not supported by the original disclosure. Per the Examiner's suggestion, "The ideal dilution is 1 vol% of the active

compound based on the volume of the vehicle" has been deleted.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 28-32 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Examiner alleges that while the specification recites "upper respiratory disorder", it disclosed that the invention is used to treat sinusitis and rhinitis. Claims 28 and 30 have been amended to recite that the "upper respiratory disorder" is selected from sinusitis and rhinitis. As stated by the examiner, there is ample support for an upper respiratory disorder selected from sinusitis and rhinitis. Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, are requested.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 28 and 31 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.

Claim 28 stands rejected for the use of the term "mixtures". Applicants note that the "s" in mixtures was deleted in the previous amendment. Perhaps the Examine could not read the cross-through the "s". The amendment is repeated herein using [] to denote the deletion.

Claim 31 stands rejected for use of the term "balanced mixtures". The "s" was deleted from mixtures in the previous amendment. Perhaps the Examiner could not read the cross-through the "s". The amendment is repeated herein using [] to denote the deletion. The term balanced is deleted herein.

For at least the foregoing reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, are requested.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 11-12, 17, 20-24, and 27-32 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over DE 2721014 to Reith (hereinafter "Reith"). Applicants respectfully traverse this rejection.

The present claims are directed to a method of treating sinusitis and rhinitis in a human or an animal in need thereof, the method comprising administering to a nasal passageway of the human or the animal a composition comprising alpha-hydroxypropionic acid and a pharmaceutically acceptable vehicle, wherein the alpha-hydroxypropionic acid is in a concentration of 0.2-4 vol.% based on the volume of the acceptable pharmaceutical vehicle, and wherein the sinusitis and rhinitis are caused by a bacterial organism or a fungal organism. Also claimed are similar methods of treating an upper respiratory disorder by administering the same composition to a nasal passageway. All of the present claims share the feature of administration to a nasal passageway.

Reith teaches a composition comprising lactic acid (i.e., alpha-hydroxypropionic acid) to treat allergies and viral diseases. Reith further teaches the composition in the form of tablets, dragees or capsules.

In making the rejection, the Examiner states "Applicant argues that there is no suggestion by Reith to treat sinusitis and rhinitis associated with bacteria and/or yeast . . . Applicant does not limit the instant method to treating only these conditions". (5252004 office action, page 4)

The present Application now claims a method comprising administering a composition comprising alpha-hydroxypropionic acid to treat sinusitis and rhinitis caused by bacterial or fungal organisms. At best Reith teaches the treatment of allergies and viral diseases. There is no teaching or suggestion in Reith that alpha-hydroxypropionic acid can be employed for the treatment of sinusitis and rhinitis caused by bacterial or fungal organisms. Reith does not provide the motivation to do what the Applicants have done. Remington does not cure the defects as this reference is relied upon only for the disclosure of vehicles for nasal administration.

An Examiner cannot establish obviousness by locating references that describe various aspects of a patent applicant's invention without also providing evidence of the

motivating force which would have impelled one skilled in the art to do what the patent applicant has done. *Ex parte Levengood*, 28 U.S.P.Q. 1300 (Bd. Pat. App. Int. 1993). The references, when viewed by themselves and not in retrospect, must suggest the invention. *In Re Skoll*, 187 U.S.P.Q. 481 (C.C.P.A. 1975). Also, the requirement for a determination of obviousness is that "both the suggestion and the expectation of success must be founded in the prior art, not in applicant's disclosure" (emphasis added). *In re Dow Chem.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). An Examiner thus cannot base a determination of obviousness on what the skilled person in the art might try or find obvious to try. Rather, the proper test requires determining what the prior art would have led the skilled person to do, with a reasonable expectation of success.

Reith teaches a composition comprising alpha-hydroxypropionic acid only for the treatment of allergies and viral diseases. Reith does not provide the motivation to use alpha-hydroxypropionic acid for the treatment of sinusitis and rhinitis caused by bacterial and fungal organisms. Reith also fails to provide an expectation of success for the Applicants' invention. Different agents require different treatments and the disclosure of a treatment for allergies and viral disease does not provide an expectation of success for the use of the same treatment of respiratory diseases caused by bacterial and fungal organisms. Thus, Reith provides neither the motivation to do what the Applicants have done nor an expectation of success for the Applicants' invention. Remington, relied upon for the teaching of vehicles for nasal administration, fails to cure the defects of Reith.

In addition, as explained previously, Reith also fails to teach nasal administration of alpha-hydroxypropionic acid and fails to teach the presently claimed amounts of the alpha-hydroxypropionic acid. Because Reith teaches only oral administration of the alpha-hydroxypropionic acid, Reith cannot provide the motivation for nasal administration of alpha-hydroxypropionic acid or the dosage amounts suitable for such administration. Reith further does not provide an expectation of success for nasal administration. As is known in the pharmaceutical arts, not all routes of administration are suitable for all active agents. The disclosure of oral administration as in Reith does not provide the motivation or expectation of success for other means of administration such as the presently claimed nasal administration.

Regarding the presently claimed dosage forms, the Examiner has alleged that "once a

method of use of a compound is known, in the absence of unexpected results, it is within the skill of the artisan to determine the optimum route of administration and concentration of the active ingredient" (5252004 office action, page 4). Applicants disagree. First, Applicants maintain that Reith does not teach the same method of use as Reith does not teach a method for treating sinusitis and rhinitis caused by bacterial and fungal organisms. Second, Reith teaches only oral administration and not nasal administration of alpha-hydroxypropionic acid. Reith teaches only the oral administration of alpha-hydroxypropionic acid in the form of tablets, dragees, and capsules. There is thus no motivation or suggestion in Reith that nasal administration would be a desirable or feasible route for administration of alpha-hydroxypropionic acid. Not all routes of administration are suitable for all active agents. Third, because Reith does not teach nasal administration of alpha-hydroxypropionic acid, Reith cannot teach the dosages that are optimal for nasal administration. Reith does not teach alpha-hydroxypropionic acid in a concentration of 0.2-4 vol.% based on the volume of the acceptable pharmaceutical vehicle. Because Reith does not address nasal administration of alpha-hydroxypropionic acid, Reith cannot teach the dosage concentration of alpha-hydroxypropionic acid useful for nasal administration. Also, Reith does not teach treatment of sinusitis and rhinitis caused by bacterial and fungal organisms and thus does not teach dosage form suitable for such treatment. Simply because an active agent is known, it is not known which dosage amount is suitable for every application and every route of administration. There is no expectation based on the teachings of Reith that alpha-hydroxypropionic acid is suitable for treatment of sinusitis and rhinitis caused by bacterial and fungal organisms or for nasal administration or that the claimed amounts would be optimal for nasal administration.

For at least the foregoing reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are requested.

In light of the foregoing amendments and remarks, reconsideration by the Examiner is respectfully requested. It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants.

TIN-0017

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Cantor Colburn LLP.

Respectfully submitted,

CANTOR COLBURN LLP

By Karen A. LeCuyer

Karen A LeCuyer, Ph.D.
Registration No. 51,928

CANTOR COLBURN LLP
55 Griffin Road South
Bloomfield, CT 06002
Telephone (860) 286-2929
Facsimile (860) 286-0115
Customer No. 23413

December 2, 2004